Academia

Alton Ochsner Medical Foundation

On October 7, 2003, the FDA's New Orleans District Compliance Officer (CO), participated in the locally sponsored annual "Responsible Conduct in Research" lecture series at the Alton Ochsner Medical Foundation in New Orleans, Louisiana. The CO presented a speech on the practical aspects of data audits to an audience of over 100 research professionals, followed by questions and answers regarding FDA's role in the clinical investigation process. This was an excellent outreach opportunity that facilitated ORA/FDA contact with research professionals in Louisiana who are actively involved in investigational trials.

University of Puerto Rico

Ajaz Hussain, Ph.D., Deputy Director of the Office of Pharmaceutical Sciences at the FDA's Center for Drug Evaluation and Research, was visiting the FDA's San Juan District Office from July 27 to July 29, 2004. On July 27, 2004, Dr. Hussain visited the University of Puerto Rico, Mayaguez Campus, to evaluate different Process Analytical Technology (PAT) research projects conducted by this Institution. He met with the University officials and made some recommendations to improve their research and educational programs. On July 29, 2004, he visited the San Juan District Office, presented an update on the PAT and the CGMP Initiative, and helped to improve district communication with the Office of Pharmaceutical Sciences of CDER.

On July 29, 2004, Dr. Hussain participated in the PAT Event "IFPAC '04 Summer Summit." IFPAC is a world-wide, not-for-profit organization dedicated to the advancement of Process Analytical Technologies. This organization sponsored a three-day symposium that was held as part of the annual meeting of the Puerto Rico Chemists Association (Colegio de Químicos de Puerto Rico) at the Westin Río Mar Resort Hotel, Río Grande, P.R. Speakers included representatives from academia, the pharmaceutical industry and the FDA.

University of Minnesota

On October 3, 2003, and October 8, 2003, the FDA's Minnesota District Office and the University of Minnesota Extension Service partnered to host low-cost workshops on acidified and low-acid canned foods for small processors. The workshops were supported by

a FY 2003 CFSAN Food Safety Education Grant. The course instructors included a Division of Field Investigation's National Food Expert, a District Public Affairs Specialist, and a University of Minnesota Extension Agent. Sixteen individuals attended the St. Paul workshop on October 6, 2003, including six small processors, extension agents, and inspectors from the Minnesota Department of Agriculture and local governments. Twenty-two individuals from small businesses, farms and orchards, the Minnesota Department of Agriculture, local governments, and extension attended the St. Cloud workshop on October 8, 2003.

Attendees received information on Federal and State regulations on acidified foods and FDA resources for small food businesses. They participated in a pH lab exercise and were able to test the pH of their own products. The workshops were well-received and the Minnesota Association of Fruit and Vegetable Growers is interested in presenting the information at their meeting in February 2004. The inspectors and extension agents will share the materials and new knowledge on acidified foods with small processors in their areas.

Associations

National Association of Area Agencies on Aging

On July 11 – 14, 2004, the FDA's Atlanta District's Public Affairs Specialist staffed Center for Food Safety and Applied Nutrition (CFSAN's) Working Globally to Protect the Nation's Food Supply floor model exhibit at the National Association of Area Agencies on Aging Annual Conference and Tradeshow. The Public Affairs Specialist worked with the Area Agency on Aging in Macon, Covington, and Kennesaw, Georgia. The Atlanta Regional Commission, one of the program's sponsors, has supported FDA programs since 1998. Comment cards received from attendees expressed their appreciation for the excellent FDA materials. "To Your Health!" was a hit! FDA distributed all 2,350 publications provided by CFSAN to the more than 1,000 conference/tradeshow participants.

Bridge & Tunnel Operators Association

On February 24, 2004, an FDA Detroit District Import Team member presented as Update on the FDA Bioterrorism Act at the Bridge and Tunnel Operators Association Annual Meeting in Detroit, Michigan. Approximately 50 individuals attended including: bridge and tunnel

operators from the Michigan/New York-Ontario border, personnel from U.S. Customs and Border Protection, U.S. Coast Guard, Canadian Border Service, Canadian Import Brokers and local congressional staffers including one from United States Senator Debbie Stabenow's (D) office. The presentation focused on Prior Notice issues and the new Compliance Policy Guide.

American Diabetes Association, American Heart Association

On February 20, 2004, the FDA's Chicago District staffed an exhibit booth at the Chicago National Woman's Heart Health Day Fair. The event was sponsored by Sister to Sister: Everyone Has a Heart Foundation, Inc., whose mission is women's heart disease prevention and screening. Governor Rod Blagojevich attended, and proclaimed the third Friday of February as "Woman's Heart Day." WGN-TV, an independent television superstation, covered the event. The event was well-attended and had many exhibitors including the American Diabetes Association, American Heart Association and Discovery Heath Channel.

Medical Alley Trade Association

On February 26, 2004, the FDA's Minnesota District gave a presentation entitled, "Where Regulatory and Marketing Intersect: FDA Requirements for Drug and Device Labeling," to 150 attendees at a Medical Alley seminar in Minneapolis, Minnesota. Medical Alley is a device and health care trade association that brings educational opportunities to its members. The presentation focused on the differences between drug and device advertising and promotional labeling regulations, and the new guidance on the brief summary, disease awareness communications, and restricted devices. Attendees were encouraged to ensure that their regulatory departments remain involved in the marketing activities. The presentation included examples of Warning Letters for advertisements and labeling. The audience appreciated the information, and asked questions on restrictions related to verbal claims in the media.

Fresh Produce Association of Americas

On October 24, 2003, the Southwest Import District's Nogales Resident Post personnel along with the U.S. Customs and Border Protection and U.S. Department of Agriculture hosted a group of representatives from the Fresh Produce Association of Americas (FPAA) and

California Farm Bureau Federation (CFBF). The group of representatives was given a brief tour of the Nogales commercial port of entry. The tour went well and FDA answered numerous questions pertaining to Federal Food, Drug and Cosmetic Act import procedures.

Catfish Processor's Association

On October 23, 2003, the New Orleans District manager gave a presentation at the 2003 Catfish Processor's Association in Starkville, Mississippi, on FDA and the catfish processor's role in food safety and security. The presentation covered the major parts of the Interim Final Rule (IFR) for Bioterrorism Act of 2002. The aspect of Registration in the IFR generated much interest and questions by the attendees. Over 130 processors, farmers, and packers were in attendance, and they represented 8 states: Mississippi, Alabama, Louisiana, Florida, North Carolina, South Carolina, Tennessee and Georgia.

States

FDA Partners with States to Warn Consumers that "Looks Can Be Deceiving"

Virginia Joins Growing List of State Partners in Effort to Educate Consumers About Unapproved Foreign Drugs; More Expected to Sign On in Coming Weeks

On April 13, 2004, FDA announced a new partnership with the Virginia Pharmacists Association to distribute consumer educational materials outlining the risks of purchasing medicines outside of FDA's regulatory scope. Over the past month, FDA has co-sponsored agreements with state pharmacists associations in Illinois, California, Texas, Maryland, New York, and Nebraska, and the Agency anticipates that additional agreements will be signed in the weeks ahead.

As part of the Agency's consumer outreach effort, FDA also recently signed an agreement with the National Community Pharmacists Association to post FDA's educational materials on the NCPA website. Additionally, FDA has partnered with drugstore chains such as Thrifty White Drug Stores, Inc. in Minnesota to support this public information campaign.

The "Looks Can Be Deceiving" education campaign uses posters, prescription bag inserts, fliers and tabletop displays to remind pharmacy customers in straightforward language that imported drugs pose a safety risk. The materials list a number of concerns, including

counterfeit drugs, untested substances, lack of quality assurance, and unsupervised use of drugs. They warn, “Looks can be deceiving. … Don’t risk your health."

“The pharmacist plays an important role in guiding patients with their medication decisions," said Carmen Catizone, Executive Director of the National Association of Boards of Pharmacy. “The ‘Looks Can be Deceiving’ program helps patients understand the problems with illegally imported drugs and provides a way to work with your pharmacist to use medications safely."

According to recent data from IMS Health, approximately $1.1 billion in pharmaceuticals were imported into the U.S. in 2003 (based on U.S. prices), despite federal laws prohibiting such actions. FDA, pharmacists, and pharmacy regulatory officials across the country are increasingly concerned about the safety risks associated with such importation.

In January 2004, FDA announced that a series of examinations conducted with the U.S. Customs and Border Protection (CBP) revealed 1,728 unapproved drugs among the 1,982 parcels inspected; this included so-called “foreign versions" of FDA-approved drugs, recalled drugs, drugs requiring special storage conditions, drugs requiring close physician monitoring and drugs containing addictive controlled substances. This "snap" inspection followed an inspection in July and August 2003, which found that 88% of the 1,153 imported drug products studied contained unapproved drugs.

Additionally, pharmacists and government officials have highlighted the potential benefits of the new Medicare prescription drug benefit for America’s seniors. When it takes effect, the prescription drug discount card will provide subsidies, discounts, and other savings to beneficiaries to help their prescription drug dollars go further.

For more information about FDA’s educational efforts surrounding the risks of drug importation, please visit FDA’s website at www.fda.gov/importeddrugs.

Alabama

On January 22, 2004, the New Orleans District managers participated in a State of Alabama Food Safety Task Force meeting held in Montgomery, Alabama. Besides FDA, in attendance were representatives from the Alabama Department of Agriculture and Industry, Alabama Department of Health, and U.S. Department of Agriculture (USDA). Topics covered included BSE, Foodborne Illness Outbreaks, and Current Activities and Initiatives. Due to potential budget cutbacks, the Alabama representatives reported that inspectional coverage may decrease in 2004. Also reported was that the Alabama Legislature is working toward adoption of a Food Code based closely on FDA’s 2001 Food Code. USDA reported that a

web site has been created in cooperation with FDA for coverage of all recalls, www.recall.gov, and FDA reported on its continued interest in chloramphenicol in imported products and the Bioterrorism Act with respect to its impact regarding registration of food firms and prior notice.

California

- The FDA's San Francisco District's Public Affairs Specialist delivered the *Take Time to Care:* Use Your Medicines Wisely program to forty employees and volunteers of the Health Insurance Counseling and Advocacy Program (HICAP), funded by the California Department of Aging, who are charged with providing information and assistance with Medicare, managed care and insurance to help seniors and other beneficiaries. The presentation, delivered on October 10, 2003, in Oakland, California, provided participants with information on safe medication usage based on the four program messages. Requests were made for hundreds of the brochures which will be distributed to HICAP clients. The program was lively with numerous questions on RX from other countries, generics and FDA's interaction with industry.

- The FDA's San Francisco District's Public Affairs Specialist gave a presentation at the California Consumer Affairs Association's Northern Division Forum in San Jose. Among the issues discussed were the prior notice interim final rule with respect to food shipments to the U.S. by individuals, the Office of Women's Health Take Time to Care about Diabetes campaign, and FDA's website as a source of current information on BSE and importation of prescription drugs from Canada. Attendees included District Attorneys (DA) and Consumer Protection Unit employees from county DA offices in northern California as well as staff from the California Department of Consumer Affairs, Consumer Action, and other local consumer advocacy organizations.

Florida

- On October 16 – 19, 2003, seven employees from the FDA's Florida District took turns staffing a Women's Health exhibit at the Southern Women's Show (estimated attendance: 30,000) in Orlando, Florida. Diabetes and weight loss publications were extremely popular, and several attendees asked about the approval/availability of Memantine (approved for Alzheimer's Disease on October 17, 2003. Several exhibitors promoted a wide variety of dietary supplement products (and some devices) with questionable health claims.

- On July 30, 2005, the Florida District's Public Affairs Specialist team, as a part of the Seminole County Healthy Kids Partnership, participated as an exhibitor at the Family Fun Festival, sponsored by the West Sanford Boys and Girls Club and the Goldsboro Front Porch. The Seminole County Healthy Kids Partnership is a collaborative effort of the FDA, the American Heart Association, the Dairy Council of Florida, the Seminole County Health Department, the Seminole County Cooperative Extension Service, the Central Florida Regional Hospital, the West Sanford Boys and Girls Club, and the Seminole County Public Schools. The 250 participants were provided with nutritional and physical fitness literature. The Central Florida Regional Hospital provided healthy snacks and bottled water. The Dairy Council of Florida arranged for T.G. Lee Dairies to provide chocolate and strawberry milk for the participants. The Seminole County Public Schools arranged for Coca Cola to provide bottled water. The American Heart Association had jump ropes for the kids, young and old, to use. Radio Disney provided hula hoops and a DJ for music and physical activity events.

Georgia

- In July 2004, the Georgia Commission on Women "Stop Osteoporosis Special" Train Excursion traveled through several rural Southwest Georgia towns participating in community health fairs. The FDA's Atlanta Public Affairs Specialist exhibited and provided information on FDA's Center for Drug Evaluation and Research's "Talk To Your Health Care Professionals. Generic Drugs Campaign. Health professionals discussed FDA's campaign with more than 300 train passengers while conducting other health screenings. Information was also provided in rural towns where community health fairs/screenings were conducted. Georgia Speaker of the House, legislators and community leaders participated in the event. More than 2,500 FDA materials were distributed.

- On February 27, 2004, the FDA Atlanta District's Public Affairs Specialist gave a presentation for the FDA at a kick-off program in Atlanta, Georgia. The presentation highlighted The Red Dress Project, the Heart Truth's national symbol for women and heart disease. The event was sponsored by the National Heart, Lung, and Blood Institute (NHLBI), a unit of the DHHS. The campaign's goal is to put a face on heart disease and motivate women ages 40 to 60 and health professionals to take heart health seriously and engage in action to reduce women's risk of heart disease. In conjunction with the American Heart Association (Southeast Affiliate), local Atlanta hospitals and sponsors, DHHS Office of the Regional Director (Region IV), FDA Southeast Region, worked together in furthering the message that "Heart Disease doesn't care what you wear --- it's the #1 killer of women." Program presenters

included representatives from DHHS OWH and DHHS Secretary-Region IV. Local media included WSB-TV 2, ABC affiliate and WXIA-TV 11, NBC affiliate.

Illinois

On July 29, 2004, the FDA's Chicago District and the Springfield Resident Post participated in a food security table top exercise at the Illinois Department of Public Health, Springfield, Illinois. The exercise was sponsored by the Illinois Food and Water Security Work Group that is comprised of individuals from federal, state, and local agencies, and industry. Approximately 60 participants worked together in small groups to meet seven objectives during the investigation of a large food borne outbreaks at a major community event in central Illinois. Communication and coordinating the investigation and sample collection/analysis was no easy task with three local health departments, four state agencies including the Illinois State Police, and at least six federal agencies, including FBI involved. In the ending all seven objectives were met, although no one guessed the cause of the outbreak (not one of the objectives), it was a success in that the participants got a real taste for what can go right and wrong during a deliberate attack on the consumer population.

Kansas

On February 3, 2004, a representative of the FDA's Kansas City District traveled with members of Region VII HHS operative divisions to meet with the Governor of the State of Kansas, and members of the legislature. The purpose of the trip was to answer questions of concern regarding Medicare, state programs in family services, and questions about drug re-importation from Canada. Kansas is another state considering Canadian drug importation for use by state employees.

Michigan

In November 2003, the FDA's Detroit District management participated in the second Michigan Agriculture and Food Security Strategy Summit. The collaborative effort from food and agricultural stakeholders has resulted in the development of seven goals such as fostering partnership between stakeholders; taking and maintaining all practical preventive actions to assure the safety and security of Michigan's food supply and agricultural

industries; collaboratively preparing economically sustainable response capabilities based on recognized emergency management principles; initiating timely, effective and well-coordinated response actions; developing the capability for rapid restoration of the safety, security and economic viability of the food and agricultural infrastructure; developing a coordinated communications plan that will address stakeholder information needs during each emergency management phase and developing a coordinated training plan that will address stakeholder training needs during each phase of the emergency management cycle.

The district provided updated information on the interim rules for Prior Notice and Registration. Many of the stakeholders expressed interest in attending the downlink, as well as the planned domestic outreach meeting. The stakeholders included representatives from Michigan Farm Bureau, Dairy, Food Processors Association, Milk Producers Association, Potato Industry Commission, Food Dealers of Michigan, Michigan Department of Agriculture, Community Health, Michigan State University, U.S. Department of Agriculture/APHIS/FSIS, and the State Police. A comprehensive document was presented to the Governor of Michigan in December 2003.

Missouri

The FDA's Regional Food Specialist gave a presentation to the Missouri Environmental Health Association about the Retail Food Program Standards. The Standards are for retail food protection programs at the state or local level and outline the elements of a complete food program. There are nine standards which address everything from Regulatory Foundation (Codes, statutes, ordinances or rules), to Resources and Employee Training. The national goal is to enroll 15% of the 3,000 state, local and tribal jurisdictions responsible for food protection. Currently there are about 110 jurisdictions enrolled. About 70 representatives of Missouri agencies attended the presentation.

New Mexico

The FDA's Denver District Public Affairs Specialist staffed an FDA exhibit at the 8th Annual New Mexico Environmental Health Association Conference in Albuquerque on October 20 – 22, 2003. The exhibit offered a variety of food safety publications and featured handouts on information on the December 12th registration deadline for food manufacturers, processors, and packers. Of the 400 attendees and exhibitors present, most work with food industry representatives, and agreed to share the information with them.

North Carolina

On October 17 – 26, 2003, the FDA's Atlanta District attended the Raleigh, North Carolina State Fair. FDA offered a "Spin at the State Fair" to hundreds of children visiting the education pavilion at the State Fair. The Raleigh Resident Post Public Affairs Specialist and other members of the 5-a-day coalition staffed an exhibit promoting good nutrition and food safety. The Education Pavilion had 10 stations and a theater for Fair goers to learn more about health and North Carolina's Agricultural products. The 5-a-day station demonstrated a balanced diet with the food pyramid, provided information on nutrition and food safety. Adults were stopped with questions such as, " Have you had your 5 today?" and " Can Your kitchen Pass the Food Safety Test?" Young children were given a "spin" on the food color wheel – a mechanical wheel on which the children picked a color, took a spin, and then identified a fruit and/or vegetable that matched their color. They were then given a color/activity book, Fight BAC stickers and BAC catchers. More than 833,000 attended this year's fair.

New York

The FDA's New York District and the Northeast Milk Specialist met with the New York State Department of Agriculture and Markets, Division of Animal Industry and the Division of Milk Control, to discuss ongoing problems with drug residues in food producing animals. Since most of the food producing animals affected are cull cows from dairy farms, and the Milk Control Division also monitors drug residues in their program area, it was agreed that FDA would collectively share information on dairy farms experiencing problems with usage of drugs in their dairy operations. It was also agreed that the parties would also participate in regional dairy cooperative meetings to discuss FDA's concerns and solicit the support of dairy farms in dealing with this problem.

Ohio

The FDA's Cincinnati District Public Affairs Specialist, in partnership with the Ohio Department of Agriculture (ODA) Food Safety Division, conducted food industry workshops in Chillicothe on October 21, 2003, and in Xenia, Ohio, on October 23, 2003. ODA covered FDA's Food Security Preventive Measures Guidance and Risk Assessment. The Public Affairs Specialist presented the requirements for Facility Registration and Prior Notice regulations. A total of about fifty people attended the workshops. These are two workshops in a series of twelve that were presented throughout Ohio to increase industry's awareness of

the new regulations going into effect December 12, 2003, and to remind industry of security measures they should be practicing to protect the food in their facilities.

Oregon

The FDA Seattle District's Portland Public Affairs Specialist participated as a partner in a press conference announcing Oregon Antibiotic Resistance Awareness Week. The conference organized by the Alliance Working for Antibiotic Resistance Education and included a statement by Mal Kohn, M.D., State Epidemiologist, Oregon Department of Human Services on the importance of the appropriate use of antibiotic treatment.

Puerto Rico

On October 1 – 2, 2003, the FDA's San Juan District's Public Affairs Specialist participated at the IV Family Health Fair sponsored by the College of Physicians and Surgeons of Puerto Rico and the local government. The activity was held at the Pavilion of Arts in the city of Caguas, Puerto Rico. Some of the conference offered at this activity were about: Breast Feeding, New Alternatives for Diabetes, Muscle Conditions, Youth health, Visual Health, How to prevent Heart conditions, How to prevent Infections, Visual problems in children, Obesity and other topics health related. Health services were also provided such as: cholesterol test, high blood pressure, AIDS, eyes exams, vaccinations for children, diabetes tests, and more. FDA's Public Affairs Specialist provided information on: women's health and diabetes, food safety, and health fraud. FDA also distributed FDA Spanish brochures with topics about health, and FDA in general. About 1,500 people stopped at the FDA booth during both days.

Tennessee

The FDA's New Orleans District's Public Affairs Specialist participated in the Senior Expo in Nashville, Tennessee, on October 8, 2003. The Public Affairs Specialist worked through the Tennessee Food Safety Task Force, Tennessee Department of Education members to gain access to a local high school to get four high school students to assist in disseminating materials to the over 2000 seniors that attended the all-day event. The students' energy in the booth, with offers of materials for seniors, coloring sheets for the seniors' grandchildren, and free stickers were well accepted by all that visited the booth.

Texas

- On October 25, 2003, the FDA's Houston Public Affairs Specialist partnered with Mt. Ararat Baptist Church and MD Anderson Cancer Center to host the breast cancer awareness play "Before Time Runs Out." The play's message was to promote detection of breast cancer early through mammography and breast self-examination. African American women in a primarily underserved area of Houston were the target audience. Breast cancer is the second leading cause of cancer death in African American women. Following the play a distinguished panel of medical experts and breast cancer survivors entertained questions concerning mammography and early diagnosis and prevention. In spite of the severe inclement weather 200+ women and men were in attendance.

- On January 31, 2004, a Public Health Service Radiation Specialist of the SWRO represented FDA at the 1st Annual "Save A Life...Save a Heritage" Community Health Fair at Southwest Center Mall in Dallas, Texas. The event was co-sponsored by Methodist Hospital Systems and The Tony B Foundation, a non-profit organization created to help meet the basic needs of Dallas area residents. There were 30 participating healthcare providers offering various health screenings and information. The event, to include live entertainment, was broadcasted by Radio One. Most consumer inquiries at the FDA exhibit concerned mammography, fibroids, menopause, diabetes, asthma, and FDA career opportunities. This health fair made it considerably easier for more than 2,700 registered individuals to obtain their health status.

Utah

The FDA's Denver District Office and The Utah Egg Quality Assurance Partnership Agreement met Smithsonian's touring food history exhibit in West Valley City, Utah (a suburb of Salt Lake City) as part of the Smithsonian's Museum on Main Street program where exhibits travel to communities across the United States. The exhibit was displayed at the Utah Cultural Celebration Center through March 2004. The exhibit featured food seminars, classes and events, along with local flavors and food-related artifacts. The Partnership Agreement was featured highlighting the progress of egg safety throughout the state along with the state's long history of being self sufficient in egg production. The state's egg production industry provided for all of their local needs as well as being able to meet the needs of surrounding states. The FDA's Denver District provided many Agency published pamphlets and posters on egg safety along with information about the Partnership Agreement as part of what will be on display.

Wisconsin

The FDA's Minnesota District's Public Affairs Specialist presented at Bioterrorism Workshops sponsored by the Wisconsin Milk Marketing Board for dairy producers held in Monroe and Appleton, Wisconsin, on October 21, 2003, and October 23, 2003. About 95 participants representing 70 dairy producers attended these half-day workshops. Presentations included an overview of the four rules on food security, an FDA perspective, and a detailed session on the specifics of facility registration.

Other Federal Agencies

FDA and SEC Work to Enhance Public's Protection from False and Misleading Statements

On February 5, 2004, FDA announced new measures designed to improve the manner by which FDA assists the Securities and Exchange Commission (SEC), whose primary mission is to protect the investing public and maintain the integrity of the securities market. In addition to implementing administrative improvements to make FDA technical and scientific support of the SEC and its staff more efficient, FDA is for the first time establishing a centralized procedure for FDA personnel to use in referring to the SEC statements by FDA-regulated firms that may be false or misleading.

Under the new referral procedure, any FDA employee who believes a publicly held, FDA-regulated firm has made a false or misleading statement to the investment public concerning a matter within FDA's authority can initiate a process for referring the matter to the SEC Division of Enforcement.

FDA's mission is to promote and protect the public health, and FDA employees will not be expected routinely to police statements by publicly held, FDA-regulated companies. However, FDA can be in a position to identify statements that may be of interest to the SEC and its staff, and FDA employees will now have a centralized procedure to make SEC referrals if, in the normal course of their activities, they come to believe that a company may have made a false or misleading statement to the investing public.

In addition to establishing this new referral procedure, the FDA is implementing the following administrative measures to improve the assistance it provides to the SEC and its staff:

1. **FDA Contacts.** FDA has identified a liaison officer as well as specific contacts within the agency's principal operational components for the SEC and its staff to use in requesting information from FDA.

Training. FDA and the SEC will engage in training in areas of mutual interest.

On December 6, 2004, FDA conducted a one-day training seminar at the SEC. FDA provided representatives from each FDA Center, the Office of Orphan Drug Development, and the Office of Combination Drug Products, and representatives from the Division of Compliance Policy, to speak on their respective center/office. FDA also prepared a 62-page training manual for the SEC entitled, “Inside the FDA.”

On March 8, 2004, the Director, Division of Compliance Policy, Office of Enforcement, issued the new procedures to FDA Contact Persons in the Centers, and others expected to be routinely involved in information sharing efforts. The Contact Persons were also notified to begin sharing using the new procedures and notified the SEC of that authorization.

Electronic Communication. FDA will use electronic media when possible, e.g., to provide information or technical support to the SEC or its staff, receive requests from the SEC for non-public information, and review statements in annual reports and other SEC filings made by FDA-regulated firms.

2. Non-Public Records/Information. FDA will provide specified FDA employees a "blanket" authorization to enable them to share non-public information with the SEC or its staff, rather than executing such authorizations on a case-by-case basis. (FDA has taken this action.) FDA and SEC staff have agreed to continue identifying additional measures that might be implemented to improve the process by which FDA shares non-public information with the SEC and its staff in accordance with FDA's laws and procedures.

FDA has been providing support to the SEC and its staff for many years. FDA assists SEC staff by assessing the accuracy of statements in SEC filings relating to FDA issues. FDA officials routinely provide technical and scientific information and expert advice to the SEC to assist in their investigations of possible violations of federal securities laws. FDA's new initiative aims to strengthen this cooperation, and make it more effective and efficient.

FDA and CBP Bolster Safeguards on Imported Food

Unprecedented Agreement Between the Agencies Advances FDA's Implementation of the Bioterrorism Act.

On December 3, 2003, FDA and the U.S. Customs and Border Protection (CBP) signed a memorandum of understanding (MOU) that allows FDA to commission thousands of CBP officers in ports and other locations to conduct, on FDA's behalf, investigations and examinations of imported foods. This unprecedented FDA-CBP collaboration significantly strengthens the implementation of the Bioterrorism Act to assure the security of imported foods.

The MOU was signed by FDA Commissioner Mark B. McClellan, M.D., Ph.D., and CBP Deputy Commissioner Douglas Browning at U.S. Customs and Border Protection headquarters in Washington, D.C.

Building on FDA's and CBP's long history of close cooperation, the MOU upgrades the two agencies' teamwork in training, day-to-day operations, and information sharing. As part of the MOU, FDA can commission all the CBP officers the two agencies consider necessary to conduct examinations and investigations in accordance with the FDA's recently issued interim final rule requiring prior notice of food imported or offered for import to the United States. FDA and CBP provided specialized training for the commissioned CBP employees who will carry out this work, and both agencies will expand their existing cooperative arrangements to directly share information affecting the safety and security of imported foods. The MOU goes into effect immediately.

To facilitate this massive undertaking regarding prior notice requirements, which involves more than 400,000 domestic and foreign firms, FDA created a new Internet system where these companies can log onto any time of the day or night, seven days a week, and register in just a few minutes.

FDA and CBP have conducted extensive domestic and foreign outreach jointly and independently, to explain the proposed rules to consumers and the food industry. In addition to holding three large public meetings via satellite downlink, FDA and CBP officials answered questions about the rules by attending six public meetings from coast to coast, delivered numerous presentations for trade groups and industry associations, and discussed the proposals with government and industry officials in Canada, Mexico, the European Union, and the Caribbean.

See: Memorandum of Understanding

USDA, FDA and DHS Sign Agreement With NASDA to Make Nation's Agriculture and Food Supply More Secure

On September 23, 2004, FDA, in partnership with the U.S. Department of Agriculture (USDA) and the Department of Homeland Security (DHS), signed a cooperative agreement with the National Association of State Departments of Agriculture (NASDA) to further develop integrated federal-state response plans for food and agricultural emergencies. This agreement advances one of the many homeland security directives set by President Bush to improve federal, state and local cooperation through enhanced response and recovery procedures in the event of a disaster.

USDA's Food Safety and Inspection Service (FSIS), FDA and HHS's Information Analysis and Infrastructure Protection are funding the development of an integrated approach to prepare for and respond to emergencies affecting national agriculture and food infrastructure.

The state departments of agriculture will gain technical expertise from FSIS, FDA and DHS officials through workgroups and tabletop exercises. Best practices and guidelines for federal and state food regulatory officials will be developed to address lessons learned from case studies and threat assessments.

The cooperative agreement will occur in three phases with the first phase starting immediately and phase three concluding by June 2005. During the first phase, a workgroup, comprised of federal, state and local officials, will gather information about existing state emergency response systems and how food/agricultural safety and security emergencies will be handled within the various states. The workgroup, during the second phase, will then develop an interagency response plan, which includes state and local participation, conduct tabletop exercises and pilots to test functionality of the emergency response plan and refine it based on lessons-learned and other input. Phase three will involve the development of guidelines for federal food and agricultural regulatory agencies to cooperate with state and local emergency response efforts, thus facilitating federal assistance to be made available more quickly and appropriately to assist the local response and recovery efforts.

Coordination and cooperation among stakeholders in food safety and security continues to be a principal commitment of the Administration as it continually strives to make greater advances in protecting the nation's food supply from intentional and unintentional threats. Additional information about food security is available on the FSIS Web page at http://www.fsis.usda.gov/Food_Security_&_Emergency_Preparedness/index.asp and FDA's Web page at http://www.cfsan.fda.gov/~dms/fsterr.html.

USDA and HHS Strengthen Safeguards Against Bovine Spongiform Encephalopathy

On July 9, 2004, Health and Human Services Secretary and the U.S. Department of Agriculture (USDA) Secretary announced three actions being taken to further strengthen existing safeguards that protect consumers against the agent that causes bovine spongiform encephalopathy (BSE, also known as "mad cow disease").

The three documents include:

- A joint USDA Food Safety & Inspection Service (FSIS), USDA Animal and Plant Health Inspection Service (APHIS) and FDA notice that asks for public comment on additional preventive actions that are being considered concerning BSE;

- An interim final FDA rule that prohibits the use of certain cattle-derived materials in human food (including dietary supplements) and cosmetics; and

- A proposed FDA rule on recordkeeping requirements for the interim final rule relating to this ban.

"The series of firewalls already in place offer excellent protection against BSE," said former Acting Commissioner of the Food and Drug Administration, Dr. Lester M. Crawford. "With these additional measures, we will make a strong system even stronger by putting into effect the most comprehensive, science-based improvements possible."

The steps already taken have been effective in protecting the American consumer from exposure to BSE. Import controls on live cattle and certain ruminant products were put in place more than 15 years ago. In 1997, FDA finalized its animal feed ban, which has been the critical safeguard to stop the spread of BSE through the U.S. cattle population by prohibiting the feeding of most mammalian protein to cattle and other ruminant animals.

USDA implemented additional measures in January to ensure that no cattle tissues known to be high risk for carrying the BSE agent are included in USDA-regulated products. Finally, as became evident last December, there is a contingency response plan, developed over the past several years, that is launched immediately to contain any potential damage after a BSE positive animal is found.

To allow interested parties and stakeholders the opportunity to comment on the additional regulatory and policy measures under consideration, USDA's APHIS and FSIS, along with the FDA, developed an advance notice of proposed rulemaking that includes several additional actions the federal government is considering regarding BSE.

The Advanced Notice of Proposed Rule Making (ANPRM) also provides the public a succinct report on the work of the international review team (IRT) convened by Secretary Veneman to review the U.S. response to the single case of BSE in the United States (in a cow imported from Canada), along with a summary of the many actions already taken by each agency on BSE.

USDA's FSIS continues to seek and address comments on actions taken in relation to the BSE mitigation measures and put in place in January 2004. FSIS is also specifically seeking comments on whether a country's BSE status should be taken into account when determining whether a country's meat inspection system is equivalent to the U.S. regulations including the provisions in the FSIS interim final rules.

USDA's APHIS is specifically seeking comments on the implementation of a national animal identification system. In April, USDA announced the availability of $18 million in Commodity Credit Corporation funding to expedite development of a national animal identification system, which is currently underway. APHIS is inviting comments on when and under what circumstances the program should move from voluntary to mandatory, and which species should be covered now and over the long term.

The ANPRM also requests comment on the following measures related to animal feed, which is regulated by FDA:

- removing specified risk materials (SRM's) from all animal feed, including pet food, to control the risks of cross contamination throughout feed manufacture and distribution and on the farm due to misfeeding;

- requiring dedicated equipment or facilities for handling and storing feed and ingredients during manufacturing and transportation, to prevent cross contamination;

- prohibiting the use of all mammalian and poultry protein in ruminant feed, to prevent cross contamination; and prohibiting materials from non-ambulatory disabled cattle and dead stock from use in all animal feed.

FDA has reached a preliminary conclusion that it should propose to remove SRM's from all animal feed and is currently working on a proposal to accomplish this goal. Comments on these issues raised in the ANPRM are due to FDA next month.

FDA also issued an interim final rule that prohibits the use of cattle-derived materials that can carry the BSE-infectious agent in human foods, including certain meat-based products and dietary supplements, and in cosmetics. These high risk cattle-derived materials include SRM's that are known to harbor concentrations of the infectious agent for BSE, such as the brain, skull, eyes, and spinal cord of cattle 30 months of age or older, and a portion of the small intestine and tonsils from all cattle, regardless of their age. Prohibited high-risk bovine materials also include material from non-ambulatory disabled cattle, the small intestine of all

cattle, material from cattle not inspected and passed for human consumption, and mechanically separated beef.

This action is consistent with the recent interim final rule issued by USDA declaring these materials to be inedible (unfit for human food) and prohibiting their use as human food.

FDA's interim final rule, in conjunction with interim final rules issued by FSIS in January 2004, will minimize human exposure to materials that scientific studies have demonstrated are likely to contain the BSE agent when derived from cattle that are infected with the disease. Consumption of products contaminated with the agent that causes BSE is the likely cause of a similar disease in people called variant Creutzfeldt-Jakob disease.

Although FDA's interim final rule has the full force and effect of law and takes effect immediately upon publication in the *Federal Register,* FDA is also asking for public comment on it.

In conjunction with the publication of the interim final rule, FDA is also proposing to require that manufacturers and processors of FDA-regulated human food and cosmetics containing cattle-derived material maintain records showing that prohibited materials are not used in their products. FDA is taking this action because records documenting the absence of such materials are important to ensure compliance with requirements of the interim final rule.

- *U.S. Department of Justice*
- *U.S. Customs and Border Protection*
- *U.S. Environmental Protection Agency*
- *U.S. Department of Agriculture*
- *Federal Emergency Management Agency*

The FDA’s New York District Office attended a multi-agency meeting on Agro-Terrorism Prevention at the U.S. Attorney’s Office in Syracuse, New York, on October 27, 2003. The multi-agency meeting was precipitated by a previous meeting between the U.S. Attorney’s Office and New York State Officials, which identified potential security gaps in the food industry. The meeting as chaired by the U.S. Attorney for the Northern District of New York, and included representatives from the following agencies: U.S. Department of Justice, U.S. Customs and Border Protection (CBP), U.S. Environmental Protection Agency, U.S. Department of Agriculture, Federal Emergency Management Agency, CBP/Agriculture Quarantine Inspection, and the Food and Drug Administration.

All agencies discussed Agro-Terrorism/Bioterrorism, and how communications are handled between the various Federal Agencies. A representative from the FDA’s New York District

Office discussed the Bioterrorism Act, including registration of food facilities and prior notice, and the working relationship with the NYS Department of Agriculture and Markets. The goal of the meeting was to develop a communication network between the involved Federal Agencies and New York State Officials on Agro-Terrorism. The U.S. Attorney stated a future meeting will be held in Albany, New York, between the involved Federal Agencies and New York State Officials, including Agriculture and Markets, the State Health Department, and the State Police.

U.S. Department of Agriculture

FDA district directors from the Cincinnati District, the Minnesota District, the Chicago District, and the Detroit District met with their U.S. Department of Agriculture/FSIS counterparts per the existing FDA/USDA Memorandum of Understanding. The meeting covered a range of topics including exchange of Dual Jurisdiction Establishments lists, imports, BSE Procedures and Policy, Tabletop Exercises and Enforcement. The meeting included the Regional Manager of the newly created (2002) OPEER (Office of Planning Evaluation and Enforcement Review) which handles enforcement activities including criminal cases. The meeting was mutually beneficial to all attendees. Local issues were discussed, emergency contact information was exchanged, greater understanding of the ever-changing FSIS structure, plans for future meetings to possibly include Animal and Plant Health Inspection Service officials.

Foreign Countries

Canada, Mexico and United States Sign Charter

On February 27, 2004, the Commissioner of FDA at that time, Dr. Mark B. McClellan, Assistant Deputy Minister of Canada's Health Products and Food Branch (HPFB) Diane Gorman, and the Federal Commissioner of Mexico's Federal Commission for the Protection from Sanitary Risks (COFEPRIS) Ernesto Enriquez Rubio announced the signing of the Trilateral Cooperation Charter.

The purpose and mission of the charter is to increase communication, collaboration, and the exchange of information among the three countries in the areas of drugs, biologics, medical devices, food safety, and nutrition. Through collaboration and information sharing on issues of mutual interest, all three countries will work together more closely to protect and promote the public health of all people in North America.

The Trilateral Cooperation serves the mutual interests of all three countries and provides a forum and a framework for participants to discuss effective means for achieving their shared public health mission. The Trilateral Cooperation establishes Working Groups, headed by three co-chairs representing each country, and the co-chairs are responsible for identifying issues for discussion and for seeking committee support.

Some of the current working groups included under the Cooperation are the:

- Canada-US-Mexico Compliance Information Group. Purpose is to increase the exchange of emergency preparedness and response, compliance and enforcement information between the three countries.

- Mexico-US-Canada Health Fraud Group. Purpose is to maintain a formal framework for cooperation in combating health fraud and to identify appropriate lines of communication to ensure a continual exchange of information on compliance and enforcement activities.

- Laboratory Cooperation Working Group. Purpose is to establish and maintain cooperation in the area of regulatory laboratory operations.

The new charter is available on-line at http://www.fda.gov/oia/charter.html.

Canada

On November 10, 2003, the FDA's New York District Office gave a presentation to 400 plus Canadian Food Exporters regarding the Bioterrorism Prior Notice and Registration Regulations in Toronto, Ontario, Canada. The presentation was a portion of a one-day seminar entitled "Profit Plus - Addressing the Challenges of U.S. Border Regulations" which was sponsored by the Ontario Ministry of Agriculture and Food and the Canadian Food Exporters Association. U.S. Customs and Border Protection also gave a presentation. At the end of the seminar, several of the speakers, including the FDA representatives, participated in a panel discussion. Many of the attendees expressed appreciation for the information provided and for the efforts of the FDA employees to educate them of the requirements of the new regulations.

Dominican Republic

The FDA's New York District Office Public Affairs Specialist worked with the Embassy of the Dominican Republic and media to alert the Dominican community on the use of Litargirio and the public health hazard. The FDA's Office of the Commissioner (OC)

requested the Public Affairs Specialist's involvement in this special project. The Public Affairs Specialist worked with the Dominican Embassy and Hispanic media to disseminate this important message. Litargirio is a powder commonly used by the Dominican community as a perspiring agent, and it was found to contain very high levels of lead.

FDA's Participates in U.S. Government's Delegation to Japan and Korea on BSE

FDA's then Acting Commissioner, Lester M. Crawford, D.V.M., Ph.D., traveled to Japan and Korea in January 2004, as part of the U.S. Government's delegation to discuss bovine spongiform encephalopathy (BSE, also known as mad cow disease) with Japanese and Korean officials.

The U.S. delegation, which discussed scientific and trade implications of the first confirmed BSE case in this country, included scientific, regulatory, and trade officials from FDA, the U.S. Department of Agriculture, and the U.S. Trade Representative.

Dr. Crawford served as the delegation's expert on all FDA-related aspects of BSE, particularly the FDA's "animal feed" rule, designed to help prevent the spread of BSE in this country by prohibiting the feeding of most mammalian protein to ruminant animals such as cows, sheep and goats. Compliance with this rule, which took effect in 1997 and is enforced by FDA, is high: more than 99 percent of the facilities that handle protein prohibited by this rule to be in ruminant feed fully comply with the regulation.

Since the first case of BSE in the U.S. was discovered in Washington state last month, FDA has focused intensely on possible improvements to this regulation that provides a crucial barrier against BSE in the U.S. In late 2002, FDA published a public notice concerning additional potential measures. That notice is available online at www.fda.gov/ohrms/dockets/98fr/110602c.htm.

Stakeholders [1/]

FDA and the National Alliance for Hispanic Health
Reaffirm Their Commitment To Support Healthy and Informed Families

On September 22, 2004, to mark the importance of Hispanic Heritage Month September 15 to October 15 2004 , FDA and the National Alliance for Hispanic Health (the Alliance) today reaffirmed their partnership and commitment for good health for Hispanic families.

[1/] Stakeholders - "appropriate scientific and academic experts, health care professionals, representatives of patient and consumer advocacy groups, and the regulated industry."

"The Hispanic family is at the core of cultural traditions and values and remains the fundamental cornerstone of the Hispanic community," said then Acting Commissioner of the FDA, Dr. Lester M. Crawford. "One important way to honor the critical role of families during this year's Hispanic Heritage Month is to help family members take the necessary steps to be healthy."

"Access to high quality health care that is affordable, as well as accurate and timely health information, are important goals to achieve to start families on the road to good health," said Dr. Jane L. Delgado, President and CEO of the Alliance.

Unique challenges confront the Hispanic community in achieving and sustaining good health. For example:

- One-third of Hispanics with diabetes are undiagnosed;
- Among all Americans with high blood pressure, Mexican Americans are less likely than whites or African Americans to know that they have it;
- Cervical cancer incidence in Hispanic women has been consistently higher at all ages than for other women; and
- Latinos living in the United States have high rates of eye disease and visual impairment, and a significant number may be unaware of their eye disease.

The FDA and the Alliance will continue to strengthen their joint effort to work with the Hispanic community to address these and other pressing concerns, and to ensure access to timely and accurate health information that will assist families to make healthy choices. To that end, these resources to assist the Hispanic families are highlighted:

FDA Meets with Stakeholders to Address Issues Related to the Implementation of the Medical Device User Fee and Modernization Act of 2002 (MDUFMA)

On December 3, 2003, FDA's Center for Devices and Radiological Health (CDRH) and its Center for Biologics Evaluation and Research (CBER) held their First Annual Stakeholder Meeting related to the implementation of the Medical Device User Fee and Modernization Act of 2002, known as MDUFMA. FDA sought feedback from members of the public during the implementation process to execute the programs and requirements of MDUFMA as effectively as possible.

The long-term goal of MDUFMA is to provide FDA's medical device program with sufficient resources to ensure that safe and effective new products get to consumers as quickly as possible. Enhanced staffing, increased training, and better infrastructure will help

FDA work more interactively and efficiently with submitters to shorten development and review time for life saving medical technologies by 2007.

FDA held this stakeholder meeting as part of its commitment to move ahead aggressively to implement the MDUFMA process fully. Already, the program is showing some short-term benefits, and FDA has made progress toward even greater long-term improvements.

MDUFMA: The First Year

The goals of MDUFMA give FDA the necessary start-up time to build infrastructure, hire, and train staff, to be able to meet performance targets that generally become applicable in 2005. As was the case with the Prescription Drug User Fee Act ten years ago, the agency utilized the first year of MDUFMA to set up the User Fee Program and establish necessary systems and procedures.

MDUFMA established ten statutory deadlines in the first year, and FDA has met all of them. Most of these requirements dealt directly with provisions of the statute other than user fee performance goals. For example, during the first year FDA

- established and staffed a new Office of Combination Products to ensure the most efficient review of products that contain a device as well as a drug or biologic component;

- published accreditation criteria, reviewed applications, and accredited 15 third parties to perform inspections;

- published a list of reprocessed single-use devices that will be subject to additional premarket requirements;

- published guidance for the submission of applications for pediatric products and for protection of children during clinical trials with medical devices.

FDA also published a number of additional guidances on a variety of the MDUFMA provisions to train staff and help industry understand the agency's process for implementing MDUFMA, including the various user fee provisions. A complete list of the guidances available, as well as other information about MDUFMA implementation, can be found at www.fda.gov/cdrh/mdufma/index.html.

To provide feedback to the public with a stake in the success of MDUFMA, including Members of Congress, FDA has several mechanisms to report on its MDUFMA progress for Fiscal Year 2003.

FDA has taken a number of steps that will contribute to its ability to meet the aggressive goals that become effective in 2006 and 2007. In addition to establishing payment, billing,

and small business designation procedures for the user fee program, FDA has invested user fee and appropriated dollars in a number of ways that will contribute to the ultimate improvement in the review process in later years. Among other actions, CDRH:

- has hired project managers for each product review group to ensure that the review process runs as efficiently as possible from the time an applicant meets with FDA;

- has hired more than 50 new scientific, medical, engineering, and other review staff, including 14 new statisticians who will be able to contribute their expertise to the review process;

- has developed a growing medical device fellowship program that hires outside clinical and academic experts to participate in FDA review work and train FDA staff, particularly in the field of cardiovascular technology;

- has developed process improvements to speed review from beginning to end, including a filing review guidance to ensure that submissions come in with the necessary information for complete review and a continuous improvement project to streamline the steps to closeout an agency decision following Panel recommendation.

In addition, the CBER report to Congress on that Center's work during the first year of MDUFMA indicates that the device program in biologics has already improved its timeliness and responsiveness.

The December 3rd Meeting with Stakeholders

The stakeholders meeting provided the opportunity for all interested persons to provide information and discuss the user fees and other aspects of the implementation of MDUFMA. This one-day meeting consisted of five panel sessions that included panelists from FDA, industry, and other stakeholders, followed by public presentations and a question and answer period from the audience at the end of each panel.